

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2137534	<b>(X3) Date Survey Completed</b> 08/08/2019
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 205 Hospital Drive Suite Q, Mc Kenzie, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) records and interview with the laboratory general supervisor, the laboratory failed to ensure the PT samples are tested in the same manner as patient samples, in 2018 and 2019. The findings include: 1) Review of the 2018 and 2019 laboratory PT records revealed that for the 2018 events one, two, three, 2019 event one all six testing personnel participated in testing the microscopic samples for the urine sediment identification, the wet mount, potassium hydroxide (KOH), and the blood cell identification. 2) Interview on August 8, 2019 at 11:00 a.m. with the general supervisor confirmed all testing personnel review all of the microscopic samples prior to the PT submission date for the events in 2018 and 2019. Each patient sample is not reviewed by all testing personal prior to reporting.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment (QA) procedure, the 2019 proficiency testing (PT) records, and interview with the general supervisor, the</p>

laboratory failed to verify the accuracy of the progesterone, follicle stimulating hormone (FSH), luteinizing hormone (LH) and estradiol, in 2019. The findings include: 1) Review of the QA procedure revealed no procedure for verifying the progesterone, FSH, LH and estradiol analytes accuracy twice a year. 2) Review of the 2019 PT records revealed no enrollment and participation for the progesterone, FSH, LH, and estradiol analytes. 3) Interview on August 8, 2019 at 1:10 p.m. with the technical consultant confirmed the progesterone, FSH, LH, and estradiol analytes were not included in the 2019 PT. Patient testing began March 27, 2019.